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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,381	03/17/2004	Jean D.A. Carruthers	D3127 RE	2839
33197	7590	03/04/2005	EXAMINER	
STOUT, UXA, BUYAN & MULLINS LLP 4 VENTURE, SUITE 300 IRVINE, CA 92618			RUSSEL, JEFFREY E	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/802,381	Applicant(s) CARRUTHERS ET AL.	
	Examiner Jeffrey E. Russel	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 22-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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1. Maintenance fees are not yet due for U.S. Patent No. 6,358,917, and therefore the reissue procedures are available for this patent.

2. The consent of assignee to the reissue and the offer to surrender have been received.

The requirement set forth in section two of the previous Office action for actual surrender of the original patent, or for submission of a statement as to loss or inaccessibility of the original patent, is WITHDRAWN in view of changes to the reissue rules. See 37 CFR 1.178(a).

3. Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 5,583,114 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

4. Claims 1-20 and 22-30 are rejected under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought. The added material which is not supported by the prior patent is as follows: Claims 5, 6, 8-10, 13, 14, 23, and 24 contain new matter because they recite intramuscularly administering Botulinum toxin, and do not specifically require that the Botulinum toxin be injected. There is no literal support in the original disclosure for the new claim limitation "intramuscularly administering". The original disclosure of the invention is limited to injection of the Botulinum toxin (see, e.g., column 2, lines 30, 46, and 49; column 3,

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lines 31-48 and 62; column 4, lines 1-3, 28-31; and the originally-filed claims) and does not disclose administration in general. More general intramuscular administration methods embraced by the current claim language would include iontophoretic delivery (see, e.g., U.S. Patent No. 5,750,141 at column 3, lines 55-62, and U.S. Patent No. 6,001,088 at column 1, lines 8-10), which are not contemplated by the original disclosure of the invention. Claims 5-11, 13, and 14 contains new matter as they recite administering Botulinum toxin to a region in proximity to each of the corners of a mouth, and do not require that the Botulinum toxin be injected to the depressor anguli oris. The original disclosure of the invention for treating downturn of corners of a patient's mouth is limited to injection into the depressor anguli oris (see, e.g., column 2, lines 29-31, 46, and 49-55; column 4, lines 1-3, 28-37; and the originally-filed claims) and does not disclose other areas in proximity of the mouth. Claims 15-20, 22, and 26 contain new matter because they do not require that the Botulinum toxin be injected into both depressor anguli oris muscles (i.e. bilateral injection), but rather embrace injection into only one of the two depressor anguli oris muscles. The original disclosure of the invention is limited to bilateral injection when injecting into the depressor anguli oris (see, e.g., column 2, lines 29-31 and 46-55; column 4, lines 22-24; and the originally filed claims). Claim 30 contains new matter because it recites further injection to an upper lip region located above a patient's mouth, but does not limit the amounts of Botulinum toxin to be injected. The original disclosure at column 4, lines 8-11, is limited to injecting a total dose in the order of 4 Units for the entire upper lip. Applicants have not indicated where the original disclosure of the invention supports the new claim language.

5. Claims 5-11, 13-20, 22-24, 26, and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. To the extent that the claims contain new matter under 35 U.S.C. 251, they also lack written description in the original disclosure under 35 U.S.C. 112, first paragraph. See the above rejection under 35 U.S.C. 251 set forth in section 4.

6. In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

“Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant.”

It is suggested that Applicants wait until all amendments have been made to the application and the application is otherwise in condition for allowance before submitting the supplemental reissue oath/declaration. See MPEP 1444 under “SUPPLEMENTAL REISSUE OATH/DECLARATION UNDER 37 CFR 1.175(b)(1)”.

7. Applicant's arguments filed January 18, 2005 have been fully considered but they are not persuasive.

With respect to the new matter rejection under 35 U.S.C. 251, the examiner intentionally included claims 1-4 in this rejection. In a reissue application, when a rejection is made under 35 U.S.C. 251, all pending claims are included in the rejection. Note that for the corresponding rejection under 35 U.S.C. 112, first paragraph, claims 1-4 are not included in the listing of rejected claims.

The new matter rejections concerning “intramuscularly administering” are maintained. As set forth in the rejections, there is no literal support for the new claim language, and the claim

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language is broadened (as evidenced by U.S. Patent Nos. 5,750,141 and 6,001,088) with respect to the original disclosure of injection. Applicants cite to sections in the specification where the words “use” and “method” occurs, and where the indefinite article “a” is used. However, for all appearances, these words are present in Applicants’ specification solely for grammatical purposes. There is no indication that these words were used to provide substantive broadening disclosure of the invention. Everywhere in the original disclosure where administration is discussed, including the same sentences in which “method” and “a” occur, the administration is limited to injection. For analogous reasons, those claims which permit injection of the botulinum toxin to a region in proximity to each of the corners of a mouth, but necessarily into the DAO muscle, are deemed to contain new matter. When the original disclosure is read as a whole, it is clear that Applicants only contemplated injection into the DAO, and did not consider any other method of administration, and did not consider any other region for the botulinum toxin to be administered. The only written disclosure of Figure 2, i.e. at column 2, lines 60-62, and column 5, lines 1-4, makes clear that the botulinum toxin is to be injected into the DAO.

The prior art rejection over the Bikhazi et al article (Otol. Head Neck Surg., Vol. 117, pages 303-307) is withdrawn in view of the amendment to claim 27. The Bikhazi et al article is limited to asymmetric injection into one DAO muscle, and does not suggest injection into each DAO muscle.

The prior art rejection over the Carruthers article (57th Annual Meeting American Academy of Dermatology, pages 21-22) in view of the Klein article (57th Annual Meeting American Academy of Dermatology, pages 20-20c) is withdrawn in view of the amendment to claim 15. The Carruthers article does not teach or suggest treating a combination of severe upper

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lip wrinkles and marionette lines and sad mouth, and therefore does not establish a prima facie of obviousness. Accordingly, it was not necessary for the examiner to re-consider the declaration under 37 CFR 1.132 by Carruthers et al filed June 11, 2001 during prosecution of parent application 09/382,002.

The prior art rejections over the Sabbaugh article (Eye World, Vol. 3, pages 37-38) are withdrawn in view of the amendment to claim 15. The Sabbaugh article does not teach or suggest treating a combination of severe upper lip wrinkles and marionette lines and sad mouth, and therefore does not establish a prima facie of obviousness.

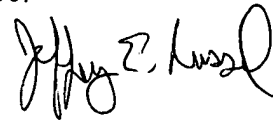
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Jeffrey E. Russel", with a stylized flourish at the end.

Jeffrey E. Russel

Primary Patent Examiner

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JRussel

February 22, 2005